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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,152	08/25/2003	Perry G. Caimi	CL2123 US NA	3625

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,152	CAIMI ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-11* is/are pending in the application.

4a) Of the above claim(s) *3,4,6,9 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,8 and 10* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/05, 05/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on 5/9/2006 withdrawing claims 3-4, 12-14, and 23-34 is acknowledged. Claims 15-22 have been cancelled. Claims 1-2 and 5-11 are pending.

Applicant's election with traverse of Group I, Claims 1-2, and 5-11, drawn to polynucleotides, vectors, host cells, and chimeric polynucleotides, and SEQ ID NO: 5 a sequence encoding an alpha (1,6)-linked glucose oligosaccharide hydrolyzing enzyme in the response filed on 5/9/2006 is acknowledged.

The traversal is on the ground(s) that there would be no burden of search for the coexamination of all the groups I-VII simultaneously. This is not found persuasive because while the search necessary for examination of all the groups overlaps it is not coextensive, examination of Group II-VII would require search of subclasses unnecessary for the search of Group I, for example 435/210; 435/41; 435/159; 435/243 and 435/274, which would impose a serious burden to the office. As restriction is clearly permissible even among related inventions as defined in MPEP 808 and 35 U.S.C. 121 allows restriction of inventions, which are independent or distinct.

Applicants also argue that all the groups have same class but different subclass, which is not persuasive because if the inventions are closely related they might have same class but have different subclass based on their independent and distinctness of the invention, as restriction is clearly permissible even among related inventions as defined in MPEP 808.

There was an error in the previous office action of placing SEQ ID NO: 24 and 25, which are peptides, in Group comprising nucleic acid sequences, should be in the group comprising

polypeptide sequences.

Applicants further traverse the SEQUENCE election requirement on the basis that the MPEP 803.04 recites that in most cases up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction and applicants submit that all the sequences should be examined together. Applicant's traversal is not found persuasive for the following reasons:

Applicant is reminded that the MPEP recites **up to 10** distinct nucleotide sequences not **at least 10** nucleotide sequences, and while applicants assert that they are claiming no more than 12 independent and distinct sequences, they are in fact claiming many more than 12 independent and distinct sequences when one considers they are claiming each of SEQ ID NOs: 1, 3, 5, 15, 26, 27, 28, 30, 32, 34, 36 and 38 and corresponding amino acid sequences. Thus applicants are claiming many more than 12 independent and distinct sequences. Besides, a sequence encoding a polypeptide having a specific function is an independent invention. Thus these inventions are distinct for the reasons given previously. "*For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02.*" (see MPEP 803). However, the examiner would also examine SEQ ID NO: 6, the corresponding amino acid sequence of SEQ ID NO: 5 (elected) and corresponding claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6, 9 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

claim.

Claims 1-2, 5, 7-8 and 10 are under consideration and are being examined herein.

Priority

Acknowledgement is made of applicants claim for priority of provisional application 60/405,896 of 8/23/2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 8/1/2005 and 5/13/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawing submitted on 8/25/2003 with this application is acknowledged.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 1-2, 7-8 and 10 are objected to as encompassing non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is directed to an isolated nucleic acid molecule encoding any alpha (1,6)-linked glucose oligosaccharide hydrolyzing polypeptide. As discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The specification teaches the structure of only a few representative species of such nucleic acid molecules encoding any alpha (1,6)-linked glucose oligosaccharide hydrolyzing polypeptides.

Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of encoding an alpha (1,6)-linked glucose oligosaccharide hydrolyzing polypeptide. Given this lack of description of representative species encompassed by the genus of DNAs used in the claim, the specification

fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 1, 5, 7-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule of SEQ ID NO: 5 encoding a polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity of SEQ ID NO: 6 from Bifidobacterium breve, does not reasonably provide enablement for any nucleic acid molecule encoding any polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity or any nucleic acid molecule hybridize any complementary region of SEQ ID NO: 5 under recited hybridizing conditions (Claim 1 part (c) and Claim 5 part (c)) having no glucose oligosaccharide hydrolyzing activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 5 are so broad as to encompass any nucleic acid molecule encoding any polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity or any nucleic acid molecule hybridize with any complementary region of SEQ ID NO: 5 under recited hybridizing conditions (Claim 1 part (c) and Claim 5 part (c)) having no glucose oligosaccharide hydrolyzing activity. Claim 2 recites the isolated nucleic acid molecule is consisting of SEQ ID NO: 5 and claim 7 recites the isolated nucleic acid molecule, wherein the alpha (1,6)-linked glucose oligosaccharide hydrolyzing polypeptide is SEQ ID NO: 6. Claim 10 recites the isolated nucleic acid molecule encoding the alpha (1,6)-linked glucose oligosaccharide hydrolyzing polypeptide, wherein the isolated nucleic acid molecule having the sequence as set forth in SEQ

ID NO: 5. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecule encoding any polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only few polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity.

The scope of the claims is not also commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules (claim 1 and 5 part (c)), which would hybridize with any complementary region of SEQ ID NO: 5 at the recited hybridizing conditions broadly encompassed by the claims.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

The specification does not support the broad scope of the claims which encompass any nucleic acid molecule encoding any polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity or any nucleic acid molecule which would hybridize any complementary region of SEQ ID NO: 5 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting glucose oligosaccharide hydrolyzing activity; (B) the general tolerance of polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid molecule encoding any polypeptide residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid molecule encoding any polypeptide having alpha (1,6)-linked glucose oligosaccharide hydrolyzing activity or any nucleic acid molecule which would hybridize any complementary region of SEQ ID NO: 5. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any nucleic acid molecule having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by EP 1227152-A (publication 7/31/2002, see IDS). EP 1227152-A discloses the sequence of a gene and encoding protein from Bifidobacterium, which is 56% identical to SEQ ID NO: 5 and 74% identical to SEQ ID NO: 6 of the instant application. EP 1227152-A also discloses cloning the gene in a vector, expressing in host cell, and method of producing the polypeptide. Because the nucleic acid sequence of the disclosure of EP 1227152-A is 56% identical, therefore, a portion the nucleic acid sequence of EP 1227152-A, would hybridize any portion of the complimentary region of SEQ ID NO: 5 under recited hybridizing condition. Since the Office does not have the facilities for examining and comparing applicants' DNA and protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed DNA and protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. This rejection of claim can be overcome by amending claim 1, part (c) by inserting "complete complimentary or fully complimentary" having glucose oligosaccharide hydrolyzing activity.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by van den Broek et al.

(GenBank Accession No. AF358444, created on 3/29/2001). van den Broek et al. discloses the sequence of a gene and encoding protein from Bifidobacterium, which is 55% identical to SEQ ID NO: 5 and corresponding amino acid sequence is 71% identical to SEQ ID NO: 6 of the instant application. van den Broek et al. also teach that the gene is an alpha-glucosidase having activity to degrade carbohydrate. Since claim 5 does not have any structural limitation, therefore, claim 5 reads any nucleic acid encoding a protein having alpha-glucosidase activity. In addition, since, the nucleic acid sequence of the disclosure of van den Broek et al., which is 55% identical to SEQ ID NO: 5 of the instant application, therefore, a portion the nucleic acid sequence of van den Broek et al., would hybridize any portion of the complimentary region of SEQ ID NO: 5 under recited hybridizing condition. Since the Office does not have the facilities for examining and comparing applicants' DNA and protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed DNA and protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

Status of the claims:

Claims 1-2, 5, 7-8 and 10 are pending.

Claim 2 is objected.

Claims 1, 5, 7-8 and 10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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